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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
REIDEL, JESSICA L	
ART UNIT	PAPER NUMBER
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/824,983	ROWLANDSON ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-20,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *42* is/are allowed.

6)☒ Claim(s) *1-4,6-10,13-20 and 41* is/are rejected.

7)☒ Claim(s) *11 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 December 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgment is made of Applicants' Amendment, which was received by the Office on December 7, 2006. Claims 5 and 21-40 have been cancelled. Claims 41-42 are new and have been added. Claims 1-4, 6-20 and 41-42 are pending.

Drawings

2. In view of the response filed December 7, 2006, the objections made to the Drawings in the Office Action of October 16, 2006 have been withdrawn. The Examiner has accepted the replacement drawing.

Specification

3. In view of the response filed December 7, 2006, the objections made to the Specification in the Office Action of October 16, 2006 have been withdrawn. The Examiner has accepted the amendments to the Abstract.

Allowable Subject Matter

4. Claim 42 is allowed.

5. Claims 11-12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The indicated allowability of claim 5 is withdrawn in view of a new interpretation of the previously applied reference to Lozier et al. (U.S. 2004/0230456) (herein Lozier). Rejections based on the new interpretations follow.

7. The indicated allowability of claim 10 is withdrawn in view of the newly discovered reference(s) to Naghavi et al. (U.S. 2003/0050538) (herein Naghavi). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102/35 USC § 103

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-2, 4, 7, 9, 13 and 15-20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lozier. As to Claims 1-2 and 17, Lozier expressly discloses a method for assessing a risk of sudden cardiac death for a patient (see Lozier Title, Abstract and page 1, paragraph 5). The method of Lozier is disclosed to comprise acquiring patient data at one of a plurality of healthcare locations (see Lozier Fig. 1 and pages 1-2, paragraphs 5-11), identifying each individual patient as being worth of an on-going assessment based on their record, read as the acquired data (see Lozier page 1, paragraph 9) and performing the on-going sudden cardiac death risk assessment in real-time whenever new patient data is acquired at any one of the plurality of healthcare locations via a clinical data manager 102 (see Lozier page 2, paragraphs 11-16 and page 3, paragraphs 16-20). Lozier further specifies that the method steps, as previously discussed, relates to a computer software system, read as a sudden cardiac death risk assessment tool. The software or sudden cardiac death risk assessment tool is specified to run via a clinical data manager, read as a patient monitor 102 for providing a

user interface, read as a display (see Lozier Fig. 3 and page 1, paragraphs 5 and 11). It is inherent that the software program or sudden cardiac death risk assessment tool, as previously discussed, would be accessed via an icon displayed on the display of the patient monitor 102 in order to start the program. In the alternative, it would have been obvious to one having ordinary skill in the art, to make the software program or sudden cardiac death risk assessment tool accessible via an icon or equivalent tool on the user interface/display of the patient monitor 102 (see Lozier Fig. 3). Clicking on an icon via a mouse or opening a software program using an icon displayed on a display is conventional and well known to those having ordinary skill in the art. Furthermore, Lozier specifies that a user of the software would have access to a mouse (see Lozier page 2, paragraph 16).

10. As to Claim 4, Lozier discloses that in addition to cardiological patient data being acquired, non-cardiological patient data such as age and gender may also be acquired (see Lozier pages 1-2, paragraphs 11-15).

11. As to Claim 7, Fig. 3 of Lozier depicts an example presentation window, read as a patient monitor 300. Lozier discloses that the cardiac risk assessment may be displayed on the patient monitor 300 which is associated with and coupled to the clinical data manager 102 at one of the plurality of healthcare locations (see Lozier pages 1-2, paragraphs 11 and 16 and page 3, paragraphs 17-20.

12. As to Claim 9, the method of Lozier is disclosed to comprise calculating a probability of sudden cardiac death for the patient based on at least one of the new patient data and a medical history of the patient. Multiple independent indications of sudden cardiac death are generated

based on the patient data from the plurality of heath care locations (see Lozier page 1, paragraph 4 and 11 and page 2, paragraphs 12-15).

13. As to Claim 15, Lozier discloses that identifying a patient as being worthy of an on-going sudden cardiac death risk assessment is based on a pre-existing condition (see Lozier page 1, paragraphs 4-9 and page 2, paragraphs 12-15).

14. As to Claim 16, the method of Lozier further comprises flagging (via color coding, a patient's name or secret coding) an identification associated with the patient if the patient is worthy of an on-going sudden cardiac death risk assessment (see Lozier page 1, paragraph 9, page 2, paragraph 12 and page 3, paragraphs 18-19).

15. As to Claim 18, Lozier discloses that the method further comprises slecting at least one input parameter (such as an electrocardiogram) upon which the on-going sudden cardiac death risk assessment is performed (see Lozier pages 1-2, paragraphs 11-15).

16. As to Claim 19, Lozier discloses that a user may sort the patient records in a desired order based upon the values contained in particular data fields (such as sudden cardiac risk data field 205). The Examiner takes the position that when patient profiles/records are listed in hierarchical order such as this, each profile adjacent to each other in the list would at least partially match (see Lozier pages 2-3, paragraph 16-20).

17. As to Claims 13 and 20, Lozier discloses that the patient data includes electrocardiogram data (see Lozier page 1, paragraph 5) and that the electrogram data may be compared to stored electrogram patterns to determine an electrogram measurement (see Lozier pages 1-2, paragraph 11). Lozier specifies that the sudden cardiac death risk assessment is based on the electrogram reading and mathematical correlation (see Lozier page 1, paragraph 9).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 3, 6, 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lozier. As to Claim 3, Lozier discloses the claimed invention as discussed above except the reference is silent to the exact phrase "automatic". Lozier does not specify that the on-going sudden cardiac death risk assessment be performed automatically. It would have been obvious to one having ordinary skill in the art at the time the invention was made to automatically perform the on-going sudden cardiac death risk assessment, since it has been held that broadly providing a mechanical or automatic means to replace manual activity, which has accomplished the same result, involves only routine skill in the art.

21. As to Claims 6 and 8, Lozier discloses the claimed invention as discussed above except that it is not specified that the plurality of healthcare locations include at least one of a hospital

information system, a patient's home, an emergency room, an operating room, a cardiology clinic, a sleep disorders clinic, a catheterization laboratory and an electrophysiology laboratory. Lozier does however specify that the locations are "clinical centers" and that the locations are capable of communicating with each other over a network (see Lozier pages 1-2, paragraph 11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the clinical centers of Lozier to include a patient's home, an emergency room, an operating room, a cardiology clinic, a sleep disorders clinic, a catheterization laboratory and an electrophysiology laboratory since it was known in the art that it may be necessary to collect information and identify a patient's risk for a disorder at all of these locations and since a hospital, an emergency room, an operating room, a cardiology clinic, a sleep disorders clinic, a catheterization laboratory and an electrophysiology laboratory are all well known types of "clinical centers".

22. As to Claim 14, Lozier discloses the claimed invention as discussed above except that it is not specified that the cardiac death risk assessment be based on measurements including at least one of blood pressure, temperature, respiration rate, carbon dioxide, oxygen saturation and weight. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Lozier to include data fields for parameters such as weight and blood pressure since it is well known in the art that an overweight patient having high blood pressure is at a higher risk for sudden cardiac death.

23. Claims 10 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lozier in view of Naghavi. Lozier discloses the claimed invention as discussed above except it is not

specified that the method include alerting a healthcare provider if the probability of sudden cardiac death is greater than a threshold.

Naghavi, however, teaches a system and method for a diagnostic observation center where the probability/risk of a person having ischemic heart disease/sudden cardiac death is compared to a threshold of 7% and if the probability/risk is greater than 7%, alerting a healthcare provider (see Naghavi pages 7-8, paragraphs 82-92). Naghavi does not explicitly state why a healthcare provider is alerted if the probability/risk is greater than 7%, but it appears that such an alert is performed in order to increase the patient's chance of seeking immediate medical attention in a life-threatening situation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Lozier, with the steps of alerting a healthcare provider if the probability/risk is greater than a threshold as taught by Naghavi, since such a modification would provide the method with an opportunity to increase the patient's chance of seeking immediate medical attention in a life-threatening situation.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to Applicants' disclosure.

25. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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